

**REMARKS**

The rejection of claims 13-19 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement is respectfully traversed.

Claim 13 is amended to recite that the method is directed to “treating” prion diseases rather than “preventing” prion diseases. Accordingly, the claims do not suffer from the concern of whether or not the total and absolute prevention of prion disease is achieved. The claim are thus enabled, at least in accordance with the statements in the recent Office Action, for instance on page 2, noting that the specification is enabling for the treatment of suppressing the proliferation of abnormal prion proteins. Reconsideration and withdrawal of this rejection are therefore respectfully requested.

The rejection of claims 1-9, 13-15 and 18 under 35 U.S.C. §102(b) as being anticipated by Richardson, *et al.* (WO 96/21437) is respectfully traversed.

As indicated in the Office Action, Richardson describes administering certain amino acids to treat abnormal movement disorders including those disorders which are secondary to treatment with neuroleptics and those which manifest themselves as part of a primary neurological disorder or disease.

Richardson is silent as to treating prion diseases or suppressing the proliferation of abnormal prion proteins as is recited in independent claims 1, 4, and 13. Suppressing the proliferation of abnormal prion proteins is also an element of independent claim 7. Thus, each of the pending claims is directed to suppressing the proliferation of abnormal prion proteins.

Because Richardson is silent as to treating prion diseases or suppressing the proliferation of abnormal prion proteins, the reference cannot anticipate the presently claimed invention. Because the claims recite the particular conditions to be treated and, in certain instances, that treatment is administered to a

patient in need thereof, the methods cannot be practiced unless one appreciates that the amino acids are effective to suppress the proliferation of abnormal prion proteins.

The law is clear that if prior art does not anticipate a use for a claimed specific condition, then the prior art does not anticipate the claim. In the case of *Perricone v. Medicis Pharmaceutical*, 77 USPQ2d 1321 (Fed. Cir. 2005), the court explained that in determining patentability the issue is not whether a prior art treatment would be effective to achieve the claimed result, instead the question is whether the prior art describes the claimed treatment.

Holding that a prior art disclosure of a topical cosmetic composition did not anticipate a claim directed to method of treating sunburn, Judge Rader stated “The issue is not, as the dissent and the district court imply, whether Pereira's lotion if applied to skin sunburn would inherently treat that damage, but whether Pereira discloses the application of its composition to skin sunburn. It does not.” Judge Rader also pointed out that “Claim 1 of the '693 patent recites a new use of the composition disclosed by Pereira, i.e., the treatment of skin sunburn . . . The disclosed use of Pereira's lotion, i.e., topical application, does not suggest application of Pereira's lotion to skin sunburn.”

Thus, in the context of the present application, the question is not whether the treatments described in Richardson would be effective to suppress the proliferation of abnormal prion proteins, rather the proper question is whether Richardson actually describes a treatment to suppress the proliferation of abnormal prion proteins in patients suffering from that condition. Because Richardson does not describe any such treatment, the claims are directed to new method of use and are therefore patentable over the reference.

Accordingly, because Richardson fails to describe that the amino acid administration is effective to suppress the proliferation of abnormal prion proteins, Richardson fails to teach each and every element of the claimed

invention and reconsideration and withdrawal of this rejection are respectfully requested.

The rejection of claims 1-9 and 13-19 under 35 U.S.C. §103(a) as being unpatentable over Richardson in view of Gordon (WO 00/64420) is respectfully traversed.

The Richardson reference is discussed above. Gordon is offered as making up for the failure of Richardson to describe the presence of prion proteins, as well as the diseases scrapie, bovine spongiform encephalopathy, and Gerstmann-Straussler-Scheinker syndrome. The Office Action assert that because Gordon teaches that these diseases are associated with the appearance of protease-resistant prion proteins in the central nervous system, it would be reasonable to treat these diseases with the same treatment.

However, neither of the references, either alone, or in the proposed combination, teach or suggest the presently claimed methods of suppressing the proliferation of abnormal prion proteins through the claimed administration of certain amino acids to a patient who is in need of this therapy. Accordingly, the proposed combination of references fails to teach all of the elements of the claimed invention and the obviousness rejection cannot be properly maintained. Reconsideration and withdrawal of this rejection are respectfully requested.

### **CONCLUSION**

In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding the preceding amendments or the application in general, a telephone call to the undersigned attorney at 202-624-

2789 would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response. Please charge any deficiency in fees or credit any overpayments to our Deposit Account No. 05-1323 (Docket No. 101551.55779US).

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Respectfully submitted,

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